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The antigenicity and safety of transgenic rice seeds which contain genetically modified Japanese cedar pollen allergens

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Background: Subcutaneous and sublingual immunotherapies have been used as a desensitizing therapy for Japanese cedar pollinosis. However, high doses of allergens may cause various adverse events including an anaphylactic reaction in both immunotherapies. Transgenic rice seeds which contain genetically modified Cry j 1 and Cry j 2, the two major allergens of Japanese cedar (JC), have been developed as immunotherapeutic candidates. However, antigenicity of Tg-rice seeds against patients with JC pollinosis was unclear. Furthermore, the safety of Tg-rice seeds for patients with JC pollinosis has not been verified, though the antigens in Tg-rice seeds were engineered such that they engage T-cell receptors but they are of insufficient length to cross-link IgE on the surface of mast cells or basophils. The aim of the present study was to prove the antigenicity and safety of Tg-rice seeds against patients with JC pollinosis.

Methods: After obtaining informed consent, blood samples were collected from patients with JC pollinosis. Allergenspecific lymphocyte proliferation test after the stimulation with Tg-rice seed extract, wild-type rice (WT-rice) seed extract, and the mixture of Cry j 1 and Cry j 2 were conducted to verify antigenicity. Furthermore, the percentage of activated basophils by Tg-rice seed extract, WT-rice seed extract, and the mixture of Cry j 1 and Cry j 2 were investigated in the basophil activation test to verify the safety of Tg-rice seeds.

Results: Allergen-specific lymphocytes in patients with JC pollinosis proliferated on treatment with Tg-rice seed extract, but not WT-rice seed extract. There was significant difference between the mixture of Cry j 1 and Cry j 2 and Tg-rice seed extract in terms of the percentage of activated basophils, though there was no significant difference between Tg-rice seed extract and WT-rice seed extract.

Conclusions: The results will contribute to estimation of the antigenicity and safety of Tg-rice seeds.